175 file Sourced

Central Intelligence Agency

Washington, D.C. 20505

DIRECTORATE OF INTELLIGENCE

25 July 1985

Japan: Government Influence on the Pharmaceutical Industry

Summary

Tokyo has not used industrial policy to target the pharmaceutical industry, although government actions have profoundly affected its growth potential. In the 1960s and 1970s, Japan's medical insurance reimbursement program encouraged excessive drug use, and thus rapid expansion of the pharmaceutical industry. Recent budget-dictated price cuts for drugs covered by the insurance program have caused the domestic industry to stagnate, however, and have reduced corporate profits. We believe the price reductions also have provided US pharmaceutical firms with an opportunity to increase their business in Japan, as Japanese firms look to joint ventures to regain momentum. Nonetheless, problems remain for foreign firms that seek to market their products in Japan. [redacted] 25X1

This memorandum was prepared by [redacted] Office of East Asian Analysis. Information available as of 25 July 1985 was used in its preparation. Comments and queries are welcome and may be directed to the Chief, Japan Branch, Northeast Asia Division, OEA, on [redacted] 25X1

EA M 85-10142

[redacted] [redacted] 25X1 25X1

[redacted] 25X1

[redacted] 25X1

Controlled Pricing

Acting on its perceived "mandate" to ensure that Japan does not suffer a repeat of the thalidomide disaster of the 1960s, the Ministry of Health and Welfare has developed complex standards and certification procedures for new pharmaceuticals that must be met before the drugs are approved for manufacture and sale in Japan. As part of its national medical insurance system, initiated in 1961, Tokyo has also devised an elaborate system for pricing prescription drugs, which some suspect restricts overseas entry of foreign firms into Japan's pharmaceutical market. Only 15 percent of the drugs in Japan are sold over the counter and, hence, priced by market forces. The costs of the remaining 85 percent--prescription drugs--are covered by the country's socialized medical system. The Health Ministry sets the maximum reimbursement that doctors who prescribe these drugs can receive. The reimbursement price for a drug is determined after comparing its effectiveness against that of similar products. [redacted] 25X1

[redacted] 25X1

Budget Problems...

Until recently, the reimbursement system, together with the pharmaceutical companies' own pricing policies, encouraged excessive use of prescription drugs. Doctors had an incentive to prescribe as many as possible because drug firms routinely sold their products to doctors at prices below the maximum reimbursement rate, allowing the doctors to profit from the difference. Such "skimming" by physicians reportedly earned them as much as 50 percent of their income. Because the state picked up the tab, patients did not object. Government medical expenditures consequently skyrocketed, reaching $55 billion in 1982, quadruple the 1972 figure, with drug sales accounting for approximately $18 billion. [redacted] 25X1

With budget problems besetting Japan, the Health Ministry has been forced to undertake several measures to curb medical expenditures:

[redacted] 25X1

25X1

- In 1983, a 1973 law providing the aged with free medical treatment was rescinded, requiring elderly patients to bear a small share of their medical costs.

- An October 1984 revision in the Health Insurance Law requires patients to bear 10 percent of total medical examination costs. The change is expected to reduce the number of patient visits to hospitals and clinics and to cut the demand for drugs.

- The Ministry has removed some drugs, including vitamins, from insurance coverage. 25X1

The Ministry's most effective move has been to reduce the official reimbursement price for prescription pharmaceuticals. The price has been cut four times, most recently by 6 percent in March, with a cumulative average reduction of 46 percent for the last four years. The 1981 cut of 18.6 percent slashed national medical expenditures by 6.1 percent. 25X1

...Affecting Industry Growth Potential

Aside from reducing the growth in national medical expenses, the reimbursement price cuts have depressed industry growth and company performance. Total 1984 pharmaceuticals production in Japan was approximately $15.9 billion, down 1.6 percent from 1983. Production in 1985 is expected to stagnate, which contrasts sharply with the double-digit growth in the 1970s. 25X1

The 1984-85 price reductions affected Japanese pharmaceutical firms more adversely than earlier cuts. When drug prices were initially lowered in 1981, drug firms could protect their profits by not reflecting the full official price reduction in the prices they charged doctors and hospitals. Thus, doctors' incomes were pinched as the differential between purchase and reimbursement prices narrowed. Recently, however, cuts have forced pharmaceutical companies to engage in competitive discounting--in terms of prices charged to physicians--to keep their market shares. Profits, therefore, have been reduced. 25X1

We believe the government has had only a minimal role in guiding the industry through its current troubles and has been a stumbling block at times. Press reports indicate that Tokyo has done no more than recommend that the industry voluntarily

25X1

[redacted] 25X1

realign its structure while raising its research and development capability and exports. According to the US Embassy in Tokyo, Health Ministry officials at the June MOSS talks said the Ministry does not solicit manufacturers' views during the decisionmaking process on price reductions. In fact, [redacted] officials of Japanese pharmaceutical companies have complained about government regulations and have pressed for measures to streamline the approval process for new drugs. [redacted] 25X1 25X1 25X1

Japanese drug firms have reacted to the profit squeeze and government advice by increasing R&D outlays. This move suggests they see greater chance of realizing profits from the new price structure if they sell new products. Major Japanese pharmaceutical companies--such as Takeda Chemical Industries, Sankyo Co., and Yamanouchi Pharmaceutical Co.--currently earmark 6 to 10 percent of annual sales for R&D. This compares with 3 percent for Japanese chemical companies and 2 percent for all Japanese industry. Major US drug firms have spent about 15 percent of sales on R&D for decades. [redacted] 25X1

As the domestic market shrinks, Japanese firms have begun to look to international sales. Tie-ups with foreign firms, ranging from R&D to sales, are increasing, and Japanese firms are beginning to set out on their own in the international market:

- Sankyo is building R&D facilities in Tokyo for gene recombination research as a base for cooperating with Du Pont and Celltech (UK) in the development of new drugs.

- Takeda has joined with Abbott Laboratories to market a Takeda antibiotic preparation in the United States.

- Yamanouchi will begin producing overseas once its exports reach $40 million a year, according to press reports. The company, which exported about $24 million in 1984, expects to attain its goal in 1986 and is conducting feasibility studies on the profitability of operating a plant in Western Europe. [redacted] 25X1

Effect on US Companies in Japan

On the basis of available evidence, we believe the Health Ministry's pricing policy is not part of an effort to restrict foreign pharmaceutical firms from the Japanese market. In our view, recent price cuts could improve US prospects in Japan, as

[redacted] 25X1

Sanitized Copy Approved for Release 2011/04/11 : CIA-RDP85T01058R000201750001-1

[redacted] 25X1

Japanese firms attempt to regain their momentum through closer links with foreign companies. [redacted] 25X1

If US firms increase links with Japanese firms, however, they may eventually encounter problems with Tokyo's unwillingness to permit the transfer of pharmaceutical licenses from US-Japanese joint ventures to wholly US-owned subsidiaries. In the April and June MOSS talks, the distinction between "friendly"--or mutually agreed on--and "unfriendly" license transfers caused problems, according to the US Embassy in Tokyo. Under current Japanese regulations, if a US company attempts to transfer the license to manufacture a drug without the Japanese partner's approval when that licensing agreement expires, the US firm must reapply for a license. The process requires regenerating and resubmitting testing data, which may involve a delay of two or more years. [redacted] 25X1

Even if Tokyo agrees to change such rules, US firms still face an uphill battle to increase their share of a stagnant market in Japan. [redacted] foreign-owned 25X1 pharmaceutical firms have increased rapidly since foreign capital participation in the industry was liberalized in 1975, but the market share of foreign-owned firms that do their own sales, promotion, and distribution in Japan stands only at 6 percent. [redacted] 25X1

If US companies can gain a foothold now, it bodes well, in our view, for future growth. The number of Japanese over 65--currently 10 percent of the population--will double in the next 30 years. This increase is certain to stimulate future demand for pharmaceuticals. [redacted] 25X1

[redacted] 25X1

[redacted] 25X1

Distribution

Subject: Japan: Government Influence on the Pharmaceutical Industry [redacted] 25X1

Original - William Barreda, Department of the Treasury
1 - Doug Mulholland, Department of the Treasury
1 - Donald Gregg, Office of the Vice President
1 - Thomas Hubbard, Department of State
1 - William Brooks, Department of State
1 - Rea Brazeal, Department of State
1 - [redacted] Defense Intelligence Agency 25X1
1 - Byron Jackson, Department of Commerce
1 - Clyde Prestowitz, Department of Commerce
1 - James Murphy, Office of the USTR
1 - Glen Fukushima, Office of the USTR
1 - [redacted] National Security Agency 25X1
1 - OEA/NAD/Japan
1 - OEA/NAD/Korea
1 - OEA/NAD/STI
1 - OEA/NAD
1 - OEA/China Division
1 - OEA/Southeast Asia Division
1 - OEA Production Office
1 - D/OEA
1 - DDI
1 - Executive Director
1 - PDB Staff
1 - NIO/EA
1 - C/PES
1 - C/DO/PPS
1 - C/EA/RR
1 - OCR/ISG
1 - NIC Analytic Group
1 - CPAS/ILS 25X1
5 - CPAS/IMC/CB
1 - [redacted]
DDI/OEA/NAD/JAPAN/[redacted] (25 July 1985) 25X1

[redacted] 25X1

Sanitized Copy Approved for Release 2011/04/11 : CIA-RDP85T01058R000201750001-1